UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte RUSSELL MICHAEL HAGAN and
KEITH THOMAS BUNCE

Appeal No. 2005-2449
Application No. 09/985,679

ON BRIEF[1]

Before WILLIAM F. SMITH, Administrative Patent Judge, McKELVEY, Senior Administrative Patent Judge, and GRIMES, Administrative Patent Judge.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to treatment of emesis (vomiting) using a combination of two known types of compounds. The examiner has rejected the claims for double patenting, nonenablement, and inadequate description. We have jurisdiction under 35 U.S.C. § 134. We reverse all of the rejections on appeal.

Background

The specification discloses that

> [t]achykinin antagonists are known to be useful in the treatment of a variety of disorders including pain, inflammatory diseases, allergic

[1] In a paper filed April 8, 2005, Appellants requested an oral hearing in this case. We have determined that an oral hearing is not necessary. See 37 CFR § 41.47(f).

> disorders, CNS disorders, skin disorders, cough and gastrointestinal disorders such as ulcerative colitis and Crohn's disease.
>
> It has now been found that tachykinin antagonists . . . are useful in the treatment of emesis.

Page 1.

"The treatment of emesis . . . includes the treatment of nausea, retching and vomiting." Page 2. "Tachykinin antagonists acting at NK_1 receptors have been found to be particularly useful in the treatment of emesis." Id. The specification discloses "[s]pecific tachykinin antagonists for use in the present invention" on pages 2-19. The specification discloses that certain compounds were determined to have NK_1-receptor antagonist activity and anti-emetic activity by use of assays known in the art. Page 25, second paragraph, and page 26, second paragraph.

"The tachykinin antagonists may, if desired, be administered in combination with one or more other therapeutic agents. . . . For example, the tachykinin antagonists may be administered with a systemic anti-inflammatory corticosteroid . . . or a $5HT_3$ antagonist such as ondansetron, granisetron or metoclopramide." Page 22.

Discussion

1. Claim construction

Claims 1-25 are pending and on appeal. Claims 1, 11, and 14 are representative and read as follows:

> 1. A method for the treatment of a mammal, suffering from or susceptible to emesis, comprising administration of an effective amount of a tachykinin antagonist which is an NK_1 antagonist in combination with one or more other therapeutic agents selected from systemic anti-inflammatory corticosteroids or $5HT_3$ antagonists.

> 11. A pharmaceutical composition for the treatment or prevention of emesis comprising a $5HT_3$ receptor-antagonist, an NK-1 receptor antagonist and a pharmaceutically acceptable carrier.
>
> 14. A method of treating or preventing emesis in a mammal, comprising administering to said mammal an anti-emetic effective amount of a pharmaceutical composition comprising a $5HT_3$ receptor antagonist, an NK-1 receptor antagonist and a pharmaceutically acceptable carrier.

Thus, claim 1 is directed to a method for treating a mammal who is suffering from or susceptible to emesis (e.g., nausea, retching, or vomiting) by administering an NK_1 antagonist in combination with either a systemic anti-inflammatory corticosteroid or a $5HT_3$ antagonist. Claim 14 is similar, but limited to administering a combination of NK_1 antagonist and $5HT_3$ antagonist. Claim 11 is directed to a pharmaceutical composition comprising an NK_1 receptor antagonist and a $5HT_3$ receptor antagonist.[2]

2. Enablement

The examiner rejected claims 1-25 under 35 U.S.C. § 112, first paragraph, on the basis that the specification does not enable practice of the claimed methods and products using the full range of NK_1 antagonists and $5HT_3$ antagonists encompassed by the claims. See the Examiner's Answer, page 6:

> Applicant fails to set forth the criteria that define those compounds useful as NK_1 antagonists, or $5HT_3$ antagonists. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. . . .[O]nly a limited number of NK_1 antagonist, or $5HT_3$ antagonist examples are set forth. . . . It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity.

[2] The specification uses the terms "NK_1 antagonist" and "NK_1 receptor antagonist" interchangeably. Compare page 2, third paragraph, and original claim 1. The same is true of "$5HT_3$ antagonist" and "$5HT_3$ receptor antagonist." See page 22, first paragraph, and original claim 12.

Appellants argue that "[a]t the time of the filing of the present application, numerous tachykinin [NK_1] antagonists were known in the art. However, it was not recognized that these compounds were useful for treating emesis. Tachykinin antagonists are described in the specification at pages 1-19 and at page 22, lines 12-14." Appeal Brief, page 3.

With regard to $5HT_3$ antagonists, Appellants argue that "[r]esearch on $5HT_3$ antagonists dates back to the 1970's when $5HT_3$ antagonists were commonly known as serotonin M antagonists." Appeal Brief, page 22 (citing six references published between 1978 and 1988). Appellants cite several patents that they characterize as disclosing specific $5HT_3$ antagonists and describing them as useful in treating nausea, vomiting, or emesis. Appeal Brief, pages 23-24.

Appellants conclude that "[t]he present invention uses known compounds (e.g., $5HT_3$ antagonists) for their known use (treating emesis) together with a second compound (an NK_1 antagonist) for a new and unexpected use (treatment of emesis). . . . Since both active ingredients of the invention can be known compounds, one of which is being used for its known use, the claimed invention is certainly enabled." Appeal Brief, page 11.

"When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application." In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

"Enablement is determined as of the effective filing date of the patent, In re Hogan, 559 F.2d 595, 604 (CCPA 1977)." Plant Genetic Systems, N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 1339, 65 USPQ2d 1452, 1455 (Fed. Cir. 2003). The effective filing date of this application appears to be September 18, 1992.

"[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" Wright, 999 F.2d at 1561, 27 USPQ2d at 1513. "The key word is 'undue,' not 'experimentation.'" In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976).

In this case, the examiner has acknowledged that the specification provides at least 20 pages of guidance regarding NK_1 antagonists. See the Examiner's Answer, page 5 ("The specification describes only the several types of NK_1 antagonists (e.g., pages 2-21 [t]herein) for use in the instant method."). The specification states that tachykinin antagonists were known in the art for treatment of various conditions. Page 1, second paragraph. The specification also cites numerous U.S. and foreign patent documents as disclosing "[s]pecific tachykinin antagonists for use in the present invention." Paragraph bridging pages 2-3. Additional prior art patent documents are cited throughout pages 3-19 of the specification.

The evidence of record therefore supports Appellants' position that NK_1 antagonists were well known in the art. Enablement does not require testing every species encompassed by a claim, even in an unpredictable art. See Angstadt, 537 F.2d at 504, 190 USPQ at 218. "Furthermore, a patent need not teach, and preferably omits,

what is well known in the art." Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1987). Since NK_1 antagonists were apparently well-known at the time the invention was made, the examiner has not adequately explained why undue experimentation would have been required to practice the claimed method with NK_1 antagonists other than those specifically exemplified.

Nor has the examiner adequately explained why combining an NK_1 antagonist with a $5HT_3$ antagonist would have required undue experimentation. The specification states that NK_1 antagonists "may be administered in combination with . . . a $5HT_3$ antagonist such as ondansetron, granisetron or metoclopramide." Page 22. The evidence of record supports Appellants' position that $5HT_3$ antagonists such as ondansetron and metoclopramide were well-known for treating or preventing emesis as of the effective filing date of this application.

For example, the entry for ondansetron in the Physicians' Desk Reference[3] states that it is " a selective 5-HT_3 receptor antagonist" (page 1069, middle column) that is "indicated for the prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy" (page 1070, middle column). In addition, Tsavaris[4] states that "[t]he most commonly used antiemetic drug is metoclopramide."

---

[3] Submitted with the Information Disclosure Statement (IDS) filed February 17, 2004. Although the examiner crossed off the IDS entry, noting "No date", each page of the copy of the PDR that was submitted bears the notation "Consult 1992 Supplements for revisions." This notation indicates that the submitted PDR was published no later than 1992 (contemporaneous with the apparent effective filing date), since a later-published PDR would have been revised to include the revisions in the 1992 supplements. The submitted PDR therefore appears to represent the state of the art as of the effective filing date.

[4] Tsavaris et al., "Diphenhydramine for nausea and vomiting related to cancer chemotherapy with cisplatin," Journal of Pain and Symptom Management, Vol. 6, pp. 461-465 (1991), submitted with the IDS filed February 17, 2004.

Page 462, left-hand column. Finally, Andrews[5] notes "[t]he recent discovery that 5-HT_3 receptor antagonists can prevent or greatly reduce severe emesis" (abstract) and states that "the unique effectiveness of 5-HT_3 receptor antagonists in preventing severe emesis evoked by a variety of anti-cancer treatments in animals suggests that 5-HT_3 receptors occupy a critical position in the emetic pathway" (page 340).

Thus, the evidence of record supports Appellants' position that both NK_1 antagonists and $5HT_3$ antagonists were known in the art as of the effective filing date of this application. The products and methods that are defined by the claims on appeal therefore appear to involve combining or administering known compounds. The examiner has not adequately explained why undue experimentation would have been required to practice the claims on appeal. The rejection for nonenablement is reversed.

3. Written description

The examiner also rejected claims 1-25 under 35 U.S.C. § 112, first paragraph, on the basis that the specification does not adequately describe the NK_1 and $5HT_3$ antagonists required to practice the claimed methods and compositions. See the Examiner's Answer, pages 4-5.

Appellants' Brief does not present any arguments on the subject of written description. This is not surprising, however, since the written description rejection was made for the first time in the Examiner's Answer. The only rejections in the previous Office action (mailed April 21, 2004) were for nonenablement and indefiniteness.

[5] Andrews et al., "Neuropharmacology of emesis induced by anti-cancer therapy," TIPS, Vol. 9, pp. 334-341 (1988), submitted with the IDS filed February 17, 2004.

Despite the fact that written description had not been raised as an issue before, the examiner did not designate the rejection as a new ground of rejection in the Examiner's Answer. Appellants apparently overlooked the new rejection and did not address it in their Reply Brief.

Normally, when Appellants have not been given a fair opportunity to respond to a rejection, the proper course of action would be to remand the application to the examiner to allow Appellants a chance to address the rejection. Here, however, we find a remand unnecessary because the rejection must be reversed.

The examiner reasoned that "[t]he specification describes only the several types of NK_1 antagonists (e.g., page[s] 2-21 [t]herein) for use in the instant method. . . . With respect to $5HT_3$ antagonists, only 3 $5HT_3$ antagonists are described (see the claims). . . . Therefore, because one of ordinary skill in the art at the time of filing Applicant's invention cannot reasonably visualize what these other '$5HT_3$ antagonists' or 'NK_1 antagonists', the written description requirements under 35 U.S.C. § 112, first paragraph, are not met." See id., page 5. The examiner cited University of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 69 USPQ2d 1886 (Fed. Cir. 2004), as supporting the rejection.

We will reverse this rejection. "The 'written description' requirement states that the patentee must describe the invention; it does not state that every invention must be described the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution." Capon v. Eshhar, 418 F.3d 1349, 1358, 76 USPQ2d 1078, __ (Fed. Cir. Aug. 12, 2005). It is not necessary to reproduce information known to those skilled in the art in order to satisfy the written

description requirement. In Capon, the Board held that claims to chimeric genes were not supported by an adequate description because the sequences of the DNA segments required to make the chimeric genes were not described in the specification. Id. at 1355, 76 USPQ2d at __. The court reversed, holding that none of the written description cases "require a re-description of what was already known." Id. at 1357, 76 USPQ2d at __.

"The Board's rule that the nucleotide sequences of the chimeric genes must be fully presented, although the nucleotide sequences of the component DNA are known, is an inappropriate generalization. When the prior art includes the nucleotide information, precedent does not set a per se rule that the information must be determined afresh." Id. at 1358, 76 USPQ2d at __.

As in Capon, the evidence in this case shows that the genera of NK_1 receptor antagonists and $5HT_3$ receptor antagonists were known to those skilled in the art. See the discussion above regarding enablement. Therefore, the specification need not describe these genera in such detail that, standing alone, it would allow those skilled in the art to visualize or recognize their members.

The examiner cited University of Rochester as supporting the rejection, but the facts of that case distinguish it from this one. In University of Rochester, the patentee claimed a method of using a compound that selectively inhibited an enzyme, but the "patent does not disclose any compounds that can be used in its claimed methods. The claimed methods thus cannot be practiced based on the patent's specification, even considering the knowledge of one skilled in the art. No compounds that will perform the

claimed method are disclosed, nor has any evidence been shown that such a compound was known." 358 F.3d at 927, 69 USPQ2d at 1895 (emphases added).

Thus, in University of Rochester, neither the specification nor the knowledge of those skilled in the art provided any description of the compounds required to practice the claimed invention. Here, by contrast, the evidence shows that those skilled in the art knew of numerous examples of NK_1 antagonists and $5HT_3$ antagonists as of the effective filing date. In view of the state of the art, the examiner has not adequately explained why the specification's description is inadequate. The rejection for lack of adequate description is reversed.

4. Obviousness-type double patenting

The examiner rejected claims 1, 2-9, 11-19, and 25 for obviousness-type double patenting on the basis that they are not patentably distinct from claims 1-4 of U.S. Patent 6,326,383. This rejection was presented in the first Office action on the merits (mailed April 5, 2002) but apparently withdrawn, since it did not appear in subsequent Office actions. Nonetheless, the examiner re-instated the rejection in the Examiner's Answer, without designating it as a new ground of rejection.

Together with the Reply Brief, Appellants filed a terminal disclaimer. The examiner has not commented on the Reply Brief or the effect of the terminal disclaimer on the obviousness-type double patenting rejection. As with the written description rejection, this would normally be a cause for remanding the application to the examiner but we find a remand unnecessary here.

To overcome a rejection for obviousness-type double patenting, a terminal disclaimer must meet the requirements of 37 CFR § 1.321(b) and (c). The relevant

parts of the rule require that a terminal disclaimer: (1) be signed by (among others) an attorney or agent of record; (2) specify the portion of the patent term being disclaimed; (3) state the present extent of the assignee's ownership interest in this application; (4) be accompanied by the appropriate fee; and (5) state that any patent granted on this application will be enforceable only if it is commonly owned with the '383 patent.

The terminal disclaimer submitted in this case is (1) signed by Gerald M. Murphy, an attorney of record; (2) specifies that "[t]he Assignee hereby disclaims the terminal part of any patent granted on the [instant] application which would extend beyond the expiration date of the full statutory term as presently shortened by any terminal disclaimer of U.S. Patent 6,326,383"; (3) states that Glaxo Group Limited is the "true owner of the entire interest" of this application; (4) was accompanied by an authorization to charge the appropriate fee (which has been charged); and (5) states that any patent granted on this application

> shall be enforceable only for and during such period that the legal title to U.S. Patent 6,326,383 shall be the same as the legal title to any patent issuing from the [instant] application, this agreement to run with any patent granted on the [instant] application, and to be binding upon the grantee, its successors or assigns.

The terminal disclaimer filed with the Reply Brief complies with the requirements of Rule 321(b) and (c) and therefore overcomes the rejection for obviousness-type double patenting. The rejection is reversed.

Other Issues

Appellants have stated that "the invention claimed in the present application is similar to the invention claimed in U.S. Patent 5,576,317 ('the '317 patent'), assigned to Pfizer. Appellants are attempting to institute an interference with Pfizer with respect to

the '317 patent." Appeal Brief, page 2. We note that several of the claims on appeal are, in fact, identical to claims in the '317 patent. The apparent effective filing date of this application is September 18, 1992, while the '317 patent has an apparent effective filing date of December 9, 1994. After this opinion is mailed, this application will be referred to the Trial Division of the Board to determine whether an interference should be declared.

Summary

The examiner has not shown that undue experimentation would have been required to practice the claims on appeal or that the specification's description of the claimed subject matter is inadequate. Appellants' terminal disclaimer overcomes the rejection for obviousness-type double patenting. Therefore, all of the rejections are reversed.

REVERSED

William F. Smith
Administrative Patent Judge

mcK

Fred E. McKelvey
Senior Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES

EG/jlb

Birch Stewart Kolasch & Birch
P.O. Box 747
Falls Chruch, VA 22040-0747